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EXAMINER

LU, FRANK WEI MIN

ART UNIT PAPER NUMBER

1634

DATE MAILED: 05/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SA

Office Action Summary

Application No.

09/461,308

Applicant(s)

AKIMOTO, TAIZO

Examiner

Frank W Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☒ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission of RCE and the amendment filed on March 22, 2004 have been entered. The claims pending in this application are claims 25-36. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of amendment filed on March 22, 2004.

Claim Objections

2. Claim 26 is objected to because of the following informality: the phrase "said specific binding substance" should be changed since "different specific binding substances" recited in claim 25 (plural) is different from "said specific binding substance" recited in claim 26 (singular).

3. Claims 27 and 28 are objected to because of the following informality: the phrase "said measurement" should be changed since there is no word "measurement" in claim 25.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 27 and 28 recite the limitation "used in the method" in the claims. There is insufficient antecedent basis for this limitation in the claims since claim 25 is directed to an apparatus and is not directed to a method. There is no method in claim 25. Please clarify.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 25-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Chee (US Patent No. 5,974,164, filed on October 16, 1995).

Chee teaches computer-aided visualization and analysis system for sequence evaluation. As shown in Figure 13, at step 702 a reference nucleic acid sequence is marked with a fluorescent dye such as fluorescein. At step 704 a sample nucleic acid sequence is marked with

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a dye that, upon excitation, emits light of a different wavelength than that of the fluorescent dye of the reference sequence such as rhodamine. At step 706 the labeled reference sequence and the labeled sample sequence are combined. At step 708 the sequences are fragmented. The fragmented nucleic acid sequences are then hybridized on a chip containing probes as shown at step 710. At step 712 a scanner generates image files that indicate the locations where the labeled nucleic acids bound to the chip. Since there is some overlap between the two signals, he performed corrections for prior to further analysis. After the corrections, the data files now correspond to "reference" and "sample". Other marks (e.g., radioactive) can be used as labels as long as the two markers are distinguishable (see Figure 13, lines 36-67 of column 24, and lines 1-18 of column 25).

Regarding claim 25, claim 25 is a "means plus function" type of claim, claim 25 only requires a first detection means, second detection means, and an analyzing means wherein these means can perform their functions respectively: (1) detecting a level of a first labeling signal emitted by a first labeling substance (ie., fluorescein) wherein said first labeling substance can label a plurality of known different specific binding substances respectively disposed at a plurality of predetermined positions on a carriers of a test piece; (2) detecting a level of a second labeling signal emitted by a second labeling substance (ie., rhodamine) wherein said second labeling substance (ie., rhodamine) differs from said first labeling substance (ie., fluorescein) and can label an organism-originated substance that binds to said specific binding substance; and (3) measuring a quantity of said organism-originated substance bound to said specific binding substance, based on the detected level of said second labeling signal and corrected for the detected level of said first labeling signal. According to MPEP 2182, "[T]he 'means or step plus

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function' limitation should be interpreted in a manner consistent with the specification disclosure. If the specification defines what is meant by the limitation for the purposes of the claimed invention, the examiner should interpret the limitation as having that meaning. If no definition is provided, some judgment must be exercised in determining the scope of the limitation." Since the specification does not specially define a first detection means and a second detection means, both specification (see page 18, last paragraph bridging to page 19, first paragraph) and Chee teach two different fluorescence dyes (see column 24, last paragraph) that can label a plurality of known different specific binding substances respectively disposed at a plurality of predetermined positions on a carriers of a test piece and can label an organism-originated substance that binds to said specific binding substance, two different fluorescence dyes taught Chee are a first detection means and a second detection means as recited in claim 25. Since the specification does not specially define an analyzing means, both specification (see page 20, last paragraph) and Chee teach scanning means (see column 6, first paragraph) that can measure a quantity of said organism-originated substance bound to said specific binding substance based on the detected level of said second labeling signal and can correct for the detected level of said first labeling signal, scanning system taught Chee is an analyzing means as recited in claim 25.

Regarding claim 28, since the analyzing means (ie., scanning system) taught by Chee is equivalent in the structure to the scanning means in the specification (see the specification, page 20, last paragraph), the analyzing means (ie., scanning system) taught by Chee can utilize a correction value calculated from information about 1) the length of the cDNA polynucleotide

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and 2) the relative frequency of the first labeling substance within each cDNA polynucleotide as recited in claim 28.

Regarding claims 26, 27, and 29-32, as shown above, since a first detection means, second detection means, and an analyzing means taught by Chee have an ability to perform functions as recited in claim 25 when said specific binding substance is a cDNA polynucleotide as recited in claim 26 or when said first labeling substance for said specific binding substance is a fluorescent dye as recited in claims 29-32, claims 26 and 29-32 are anticipated by Chee. Since the analyzing means taught by Chee have an ability to utilize a correction value calculated for each specific binding substance as recited in claim 27, claim 27 is anticipated by Chee.

Regarding claims 33-36, since Chee teaches that other labels (ie., radioactive) can be used as long as two markers is distinguishable, claims 33-35 are anticipated by Chee.

Therefore, Chee teaches all limitations recited in claims 25-36.

Response to Arguments

I. Related to applicant's arguments filed on October 22, 2003 (see applicant's remarks, see pages 6, first paragraph bridging to page 7, first paragraph).

The examiner has answered these arguments in the advisory action mailed on January 22, 2004 (see the advisory action).

II. In page 8, first paragraph bridging to page 9, second paragraph of applicant's remarks, applicant argues that: (1) "the presently claimed apparatus is not taught by Chee, and the apparatus of Chee cannot perform the function of the present invention" since "[C]hee does not disclose any labeled member disposed on a test piece, and Chee does not show two labeled binding substances that hybridize to each other."; and (2) "claim 25 recites an analyzing means

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for measuring a quantity of said organism-originated substance bound to said specific binding substance based on the detected level of said second labeling signal corrected for the detected level of said first labeling signal. Chee does not teach an analyzing means with these limitations. The scanning means of Chee (cited by the Examiner in Col. 16, first paragraph) does not correct the value of one signal based on the detected level of another”.

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, as shown in the office action, Chee teaches a first detection means, a second detection means, and an analyzing means recited in claims 25-36. Second, claim 25 only requires structural limitations comprising a first detection means, a second detection means, and an analyzing means, and “any labeled member disposed on a test piece”, “two labeled binding substances that hybridize to each other”, and “measuring a quantity of said organism-originated substance bound to said specific binding substance based on the detected level of said second labeling signal corrected for the detected level of said first labeling signal” argued by applicant are not structural limitations but are functional limitations. Therefore, applicant’s arguments are not directed to structures of the apparatus taught by Chee but appear to argue functions of apparatus taught by Chee. It is known that, while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board’s finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA

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1971); *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987) (see MPEP 2114). Since Chee teaches all structural limitations recited in claims 25-36 (see above rejection), claims 25-36 are anticipated by Chee.

Conclusion

9. No claim is allowed.
10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703)872-9306 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.



Frank Lu
PSA
May 13, 2004

FRANK LU
PATENT EXAMINER

1.